

08/982,965



UNITED STATES DEPARTMENT OF COMMERCE

Patent and Trademark Office

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VB

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/982,965	12/02/97	LOWELL	G 359292000110
EXAMINER			

HM12/0705

JOHN F MORAN
OFFICE OF COMMAND JUDGE ADVOCATE
HQ USAMRDC DEPT OF THE ARMY
FORT DETRICK
FREDERICK MD 21702-5012

BUREAU	PAPER NUMBER
ART UNIT	15

1648

DATE MAILED: 07/05/00

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 4/21/00

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three (3) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-4, 6-9 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1-4, 6-9 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☒ The specification is objected to by the Examiner.
☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.
☐ received in Application No. (Series Code/Serial Number) _____
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____
☐ Interview Summary, PTO-413
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES--

BEST AVAILABLE COPY

Serial No. 08/982,965
Art Unit 1648

The Art Unit location of your application in the Patent and Trademark Office has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1648.

5 The status of the related application(s) cited at the first page of the specification should be updated, if necessary, to ensure a properly completed file record. It is noted that the filing papers of the instant application indicated that this application is a divisional of application Serial No. 08/143,365, now U.S. Patent No. 5,726,292. However, Applicant's amendment to
10 the first line of the specification indicates that the application is a "continuation of application U.S. Serial No. 143,365" and further claims priority to additional parent applications. Applicant should correct the inconsistency and add the correct
15 series number, i.e., 08/143,365, at the first line of the specification. Further, Applicant is again reminded that Applicant is **required** to file a request for correction of the filing receipt since the file wrapper does not properly refer to the parent applications.

20 The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

 Applicant's Raw Sequence Listing has been entered in the file record. Applicant should note that the Office made minor corrections to the Raw Sequence Listing in order to allow entry of
25 the Raw Sequence Listing.

 Applicant's request for a Continuing Prosecution Application is acknowledged. Accordingly, FINALITY of the last Office Action is withdrawn.

 Applicant's request for entry of the Amendment After Final

Rejection, Paper No. 11, filed December 22, 1999 is acknowledged. The Amendment has been entered pursuant to Applicant's request for a Continuing Prosecution Application, Paper No. 14, filed April 21, 2000. In view of Applicant's Request, the status of the claims is as follows: Claim 5 has been canceled; Claims 1-4 and 6-9 are currently pending before the Examiner.

The oath or declaration remains defective. A new oath or declaration in compliance with 37 C.F.R. 1.67(a) identifying this application by its Serial Number and filing date is required. See M.P.E.P. 602.1 and 602.02. The oath or declaration is defective because:

- (1). It does not state that the person making the oath or declaration in a continuation-in-part application filed under the conditions specified in 35 U.S.C. § 120 which discloses and claims subject matter in addition to that disclosed in the prior copending application, acknowledges the duty to disclose material information as defined in 37 C.F.R. 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.
- (2). Applicant has not given a post office address anywhere in the application papers as required by 37 C.F.R. 1.33(a). A statement over Applicant's signature providing a complete post office address is required. Further, Applicant's residence address is illegible.
- (3). The continuation data as presently amended at the first line of the specification is not consistent with any claims for priority set forth in the Oath and Declaration. Applicant should submit a new oath properly claiming priority to the appropriate parent applications.

Further, Applicant is **required** to request a corrected filing receipt setting forth the continuation data and the relationship of the parent applications to the instant application to properly complete the file wrapper.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 and 6-9 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is vague and indefinite in the recitation "is further enhanced by at least about 1.5 fold..." since it is entirely unclear what amount of enhancement would be encompassed within the metes and bounds of the claimed invention. Amendment of claim 1 to more particularly point out and define what is intended to be encompassed by the claim language would obviate this rejection. Claims 1 and 6-7 are vague and indefinite in the recitation "about 1:1 and 1:20" or similar language, since it is unclear precisely what range is being encompassed by the claims. Amendment of claims 1 and 6-7 to delete "about" would obviate this rejection.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 and 6-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

5 skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim language "which is further enhanced by at least about 1.5 fold with an adjuvant" does not find literal support in the specification. The specification does not set forth any specific ranges of enhancement that the Examiner has found. Applicant is invited to point to specific support in the specification for the invention as now claimed.

10 Upon review of Applicant's parent application, 07/065,440, Applicant **IS NOT** accorded benefit of the filing date of the earlier filed application. The specification of application Serial No. 07/065,440 does not provide support for gp160-proteosome complexes as presently claimed.

15 Claims 1-4 and newly added claims 5-9 remain rejected under 35 U.S.C. § 103 as being unpatentable over Lowell et al. (U) or Lowell et al. (V) or Smith et al. (W) or Avraham et al. (X) in view of Ratner et al. (Y) for the reasons of record set forth in the last Office Action. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection. Applicant
20 reiterates previous arguments that the rejection constitutes an "obvious to try" argument and that the references are not prior art to the instant application (see Paper No. 11, pages 4-5).

25 With respect to the references not being prior art based on the earlier filing date of parent application Serial No. 07/065,440, as stated above, Applicant has not been accorded benefit of the earlier filing date of the parent application.

30 With respect to the "obvious to try" argument, as stated in the last Office Action, Applicant's claims are only directed to compositions and methods for inducing antibodies. As gp160 is a large protein and since proteosomes were known in the art to

enhance immunogenicity, one of ordinary skill in the art would have reasonably concluded that a composition of gp160 and proteosomes would reasonably give rise to antibodies specific for gp160. Further, Lowell et al. (U) teach that "the proteosome system has potential as an important vehicle to enhance the immunogenicity of peptide vaccines in general" (see page 802, column 2, last sentence, emphasis added). Lowell et al. (V) teach "Since proteosomes have been safely given to many people and since important antigenic determinants are generally hydrophilic, this system should be widely applicable to the development of peptide vaccines for human use" (see page 662, first full paragraph, emphasis added). Thus, Applicant's own prior work teach the broad application of proteosomes to vaccine production. Therefore, the prior art provides a reasonable expectation of success and does not constitute an "obvious to try" argument. The rejection is deemed proper and is maintained.

No claim is allowed.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. The Fax number is (703) 308-4242. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Robert D. Budens at (703) 308-2960. The Examiner can normally be reached Monday-Thursday from 6:30 AM-4:00 PM, (EST). The Examiner can also be reached on alternate Fridays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, James Housel, can be reached at (703) 308-4027.

Any inquiry of a general nature or relating to the status of

Serial No. 08/982,965
Art Unit 1648

this application should be directed to the Group receptionist at
(703) 308-0196.



Robert D. Budens
Primary Examiner
Art Unit 1648

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rdh
June 30, 2000